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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,470

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Rakesh Chibber

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EXAMINER

LEWIS, PATRICK T

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

02/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,470	Applicant(s) CHIBBER, RAKESH	
	Examiner Patrick T. Lewis	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 77-153 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 77-153 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06262008; 11192007; 07102007; 03302007;</u> | 6) <input type="checkbox"/> Other: ____. |
| <u>02092007; 06222006.</u> | |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 77-95, 101-122, 131-143, and 146-151 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 11/481,255. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The examined claims are either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that is recited in claims 1-28 of copending Application No. 11/481,255.

Art Unit: 1623

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 77-120, 123-142 and 146-151 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 11/481,256. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The examined claims are either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that is recited in claims 1-27 of copending Application No. 11/481,256.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 77-153 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 11/980,727. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The examined claims are either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that is recited in claims 1-23 of copending Application No. 11/980,727.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101/112

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 148-150 and 153 provide for the use of a compound, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 148-150 and 153 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1623

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 77-81, 85-94, 131-143, 146-151 and 153 are rejected under 35 U.S.C. 102(b) as being anticipated by Mimaki et al. *Phytochemistry* (1996), Vol. 42, pages 1065-1070 (Mimaki).

Mimaki teaches new steroidal saponins **1-5** (page 1067). The isolated saponins and their derivatives were evaluated for an *in vitro* antitumour-promoter activity by measurement of their inhibitory activity on TPA-stimulated ³²P-incorporation into phospholipids of HeLa cells (Table 2). This is known to correlate well with antitumour-promoter effects *in vitro*. Compounds **1** and **3** inhibited the phospholipid metabolism, while the aglycones (**1a** and **3a**) and the furostanol saponins (**4** and **5**) did not act as inhibitors. The spirostanol saponins (**2** and **2a**) were cytotoxic towards HeLa cells at 50 µg/ml.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1623

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 82-84, 90-130, 144-145 and 152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mimaki as applied to claims 77-81, 85-94, 131-143, 146-151 and 153 above in view of Matsuda et al. Bioorg. Med. Chem. Lett. (2003), Vol. 13, pages 1101-1106 (Matsuda) and Friedman et al. Food and Chemical Toxicology (2003), Vol. 41, pages 61-71 (Friedman).

Although Mimaki does not teach all of the compounds embraced by the instant formula I, such compounds were known in the art at the time of the invention.

Matsuda teaches that steroid saponins (isolated from the rhizomes of plants of the genus *Paris*) have gotten scientific attention because of their structural diversity and significant biological activities, such as hypocholesterolemic, antitumor, antidiabetic,

Art Unit: 1623

antiinflammatory, inhibitory activities against platelet aggregation and cAMP phosphodiesterase, and antifungal (page 1101). It was found that the methanolic extract from the rhizomes of *Paris polyphylla* SM. var. *yunnanensis* (FR.) H-M. showed protective effects against ethoanol-induced gastric mucosal lesions in rats. By bioassay-guided separation, four known spirostanol-type steroid saponins (**1-4**), a new furostanol-type steroid saponin (**5**), together with two known furostanol-type steroid saponins (**6** and **7**) were isolated from the active fraction. As shown in Table 2, spirostanol-type steroid saponins, pennogenin 3-O-glycosides (**1** and **2**) and diosgenin 3-O-glycosides (**3** and **4**) showed potent protective effects on ethanol- and indomethacin-induced gastric lesions in rats. Matusuda further teaches pennogenin (**8**) and diosgenin (**9**).

Friedman teaches the glycoalkaloids solanine, chaconine, solasonine, and tomatine (page 63). Glycoalkaloids and aglycones may have beneficial effects (page 62). Glycoalkaloids are reported to inactivate the *Herpes simplex*, *Herpes zoster*, and *Herpes genitals* viruses in humans, to protect mice against infection by *Salmonella typhimurium*, to enhance the duration of action of anesthetics, and to potentiate the immune response of vaccines in mice.

Although Mimaki does not explicitly teach all of the compounds embraced by instant formula I, as shown by Matsuda and Friedman, such compounds were known in the art at the time of the invention. As shown by Matsuda, steroid saponins have gotten scientific attention because of their structural diversity and significant biological activities, such as hypocholesterolemic, antitumor, antidiabetic, antiinflammatory,

Art Unit: 1623

inhibitory activities against platelet aggregation and cAMP phosphodiesterase, and antifungal. The phrase "treatment of a condition associated with raised activity of the enzyme core 2 GlcNAc-T" embraces a multitude of disease states. One of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in using a steroid saponin for treating at least one condition for which this class of compounds has been found useful such as treating cancer, diabetes or inflammation.

Conclusion

14. Claims 77-153 are pending. Claims 77-153 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patrick T. Lewis/
Primary Examiner, Art Unit 1623

/PL/